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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,988	12/28/2001	Ronald J. Pettis	500752999021	4336

20583 7590 06/23/2009

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EXAMINER	
MENDEZ, MANUEL A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/028,988	PETTIS ET AL.	
	Examiner	Art Unit	
	Manuel A. Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/29/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Introduction

The examiner of record performed a complete review of the prior art submitted in the IDS dated January 29, 2009. Importantly, the examiner considers the Gross, Prausnitz, and Srivastava patent to be of particular relevance to the prosecution of this application, and therefore, invites applicant to present comments on the merits of the following rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross** (US 5,527,288) in view of **Prausnitz** (US 6,611,707), in further view of **Srivastava** (US 6,007,821), and in further view of **Yuzhakov** et al. (US 6,256,533; hereafter Yuzhakov).

As stated in the in the Office Action dated 11/26/2008 of U.S. Application No. 10/028,989:

Gross discloses an intradermal compartment drug delivery device that includes administering a substance through a small gauge hollow needle. The length of the needle is between 0.3 to 3.0 mm. Gross discloses that "the drug is delivered directly to a capillary-containing tissue and has no barriers to pass through before entering the vascular system". This capillary-containing tissue

is the intradermal compartment even though that term is not used in Gross' specification.

The diameter of the needle is 0.1- 0.2 mm. The substances for injection include a variety of substances that include peptides, proteins, hormones, insulin, nucleic acids, and hydrophobic and hydrophilic compositions. As shown in figure 3, the needle is inserted perpendicularly into the skin. Means for actively discharging the drug include an infusion pump. The disclosure also indicates that the device can be used to deliver a bolus injection. Examples 1 and 2 disclose an infusion flow rate of 0.1 ml/min.

Gross meets the claim limitations as described above but fails to include that the needle has an outlet with an exposed height of between 0mm-1mm. However, Prausnitz teaches the use of needles with a zero exposed height to deliver drugs into the skin. Accordingly, at the time of the invention, it would have been obvious to use the teaching of the exposed outlet of Prausnitz in the invention of Gross in order to provide a known flow dynamic as desired from the end of the needle. The zero exposed height as disclosed by Prausnitz would be known by one skilled in the art to provide a substantially longitudinally directed flow as opposed to a radially directed flow component as found in beveled needles with liquid exits the needle opening. Gross meets the claim limitations as described above but fails to include that the dosage of the substance for achieving a systemic bioavailability is reduced by at least 10%-30% compared to when the substance is delivered to a subcutaneous compartment. However, Srivastava discloses a method for treatment of autoimmune disease that includes the teaching that "while both subcutaneous and intradermal routes of administration are effective, intradermal injections typically require a lower dosage and are, therefore, preferred with respect to economy of materials.

Additionally, the use a microneedle array for drug infusion would have been considered conventional in the art based on the teachings of Yuzhakov. This patent demonstrates the conventionality of using arrays for the topical delivery of drugs.

Additionally, the specification states:

The thin layer of stratum corneum represents a major barrier for chemical penetration through skin. The stratum corneum is responsible for 50% to 90% of the skin barrier property, depending upon the drug material's water solubility and molecular weight. The epidermis comprises living tissue with a high concentration of water. This layer presents a lesser barrier for drug penetration. The dermis contains a rich capillary network close to the dermal/epidermal junction, and once a drug reaches the dermal depth it diffuses rapidly to deep tissue layers (such as hair follicles, muscles, and internal organs), or systemically via blood circulation.

Based on the above observations, for a person of ordinary skill in the art, modifying any microneedle array to infuse drugs based on the parameters disclosed by the **Gross, Prausnitz, and Srivastava patents would have been considered obvious in view of the proven conventionality of these infusion systems, and moreover, because such arrays provide for enhanced drug delivery.**

Finally, during the infusion process, the variation of the molecular weights of macromolecular pharmaceutical substances would have been considered "obvious to try" since these enhancements were readily available technologies at the time the invention was made, and therefore, would have allowed the artisan to choose from a finite number of predictable solutions, as described by the teachings of the above cited patents, with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM